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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

7590 11/23/2001

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EXAMINER

DAVENPORT, AVIS MICHELLE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/23/2001

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/269,845	Applicant(s) JANUSZ ET AL.	
	Examiner Avis M. Davenport	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7, 9-11, 13-17, 19-22, 24, 26-36, 38, 40, 41, 44, 46, 47 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9-11, 13-17, 19-22, 24, 26-36, 38, 40, 41, 44, 46, 47 and 51-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request for continued Examination as set forth in the communication filed 7/30/01 is accepted.

Claims 3-7, 9-11, 13-17, 19-22, 24, 26-36, 38, 40, 41, 44, 46, 47, and 51-56 are pending in the instant application. Claim 31, 35, and 41 have been amended, claim 12 has been canceled and claims 56-57 have been added as requested by applicants in the communication filed 7/30/01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 40, 44, 47, 53 and 57 provides for the use of Colostrinin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 40, 44, 47, 53 and 57 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim

which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 6-7, 10, 11, 14-17, 20-21, 24, 31, 34, 40, 44, 46, 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected for the following reasons:

(1) The terminology "and/or" is indefinite. The language should be removed.

(2) The terminology "predetermined amount" is indefinite as set forth. The proper language for a composition or method claim is "in an effective amount" applicants should also include what the amount is effective to treat. Please correct.

(3) The terminology "having the composition and amino acid sequence..." or in claim 54, "having the composition ..." is confusing. The amino acid sequences

set forth should only state "amino acid sequence" terminology, the sequences are not compositions. Please correct.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-7, 9-11, 13-17, 19-22, 24, 26-36, 40-41, 44, 46-47, and 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janusz et al.

The Janusz reference teaches that Colostrinin can be used to treat immune disorders. The reference discloses the treatment in mice as a model.

The instant invention is drawn to the use of Colostrinin in medicaments for the treatment of immune disorders and other conditions. In claims such as 24, 31, 46 and 57 the claim reads on humans.

The difference in the prior art and the instant invention, if there is one, is the disease conditions claimed and the use of the mouse model.

It would have been *prima facie* obvious to one of ordinary skill in the art to use a known model such as mice for experimental data as set forth in the prior art. The mouse model is a well known tool in the therapeutic art area. One would expect the therapeutic efficacy to extrapolate to humans in the absence of a showing of unexpected results. The terminology immune disorder is very broad and includes many disorders including chronic disease states, infections, bacterial and viral diseases and some neurological disorders which can include the central nervous system. The instant invention disorders and diseases can not be excluded from the immune disorder pathway of action or modes of operation. One would expect the immune disorder "umbrella" of conditions and diseases to encompass the instant invention disorders, diseases, and conditions in the absence of a showing of unexpected results.

The references of Staroscik et al., Hraba et al., and Zimecki et al. have been cited to further illustrate the state of the art.

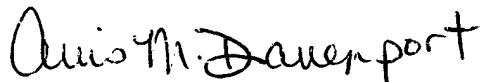
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis M. Davenport whose telephone

number is (703) 308-4002. The examiner can normally be reached on T-F(10:00-8:00) Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Avis M. Davenport
Primary Examiner
Art Unit 1653

amd
November 19, 2001